UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF ILLINOIS

IN RE YASMIN AND YAZ (DROSPIRENONE): MARKETING, SALES PRACTICES AND RELEVANT PRODUCTS LIABILITY LITIGATION	**3:09-md-02100-DRH-PMF MDL No. 2100**
	Judge David R. Herndon
	COMPLAINT AND JURY DEMAND
SELENA SYKES 217 Miers Road Winona, MS 38967, Plaintiff, vs. BAYER HEALTHCARE PHARMACEUTICALS INC. and BAYER PHARMA AG, Defendants.	Civil Action No.: 3:11-cv-12578-DRH -PMF

COMPLAINT

Plaintiff Selena Sykes (hereinafter referred to as "Plaintiff"), an individual, files this Complaint seeking judgment against Defendants Bayer Healthcare Pharmaceuticals, Inc. and Bayer Pharma AG (hereinafter referred to as "Defendants), for injuries and damages caused by her ingestion of Yaz® and/or Yasmin®, (generically as drospirenone and ethinyl estradiol) a combination oral contraceptive prescription medication and, in support thereof, states and alleges as follows:

PARTIES AND JURISDICTION

1. Plaintiff Selena Sykes is a resident and citizen of Winona, Mississippi, located in Montgomery County.

2. Plaintiff Selena Sykes was prescribed and purchased and ingested the prescription contraceptive medication product titled Yaz® and/or Yasmin® (hereinafter referred to as Yaz®/Yasmin®), and suffered gallbladder injury resulting in the removal of her gallbladder on or about May, 2007 as a proximate and direct result of using Yaz®/Yasmin®, which was designed, developed, marketed, advertised and distributed by Defendants herein.

3. Plaintiff alleges an amount in controversy in excess of Seventy-Five Thousand Dollars ($75,000.00), exclusive of interest and costs.

4. Bayer Corporation is an Indiana corporation with its principal place of business at 100 Bayer Road, Pittsburgh, Pennsylvania 15205. Bayer Corporation is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drugs Yaz®/Yasmin®.

5. Defendant Bayer Healthcare Pharmaceuticals, Inc. is a Delaware corporation, with its principal place of business at 6 West Belt Road, Wayne, New Jersey, 07470. Bayer Healthcare Pharmaceuticals, Inc. was created by the integration of Bayer Healthcare and Berlex, Inc. (formally known as Berlex Laboratories, Inc.). As a result of the acquisition, Defendant Bayer Healthcare Pharmaceuticals, Inc. is obligated for its predecessor's liabilities. Bayer Healthcare Pharmaceuticals, Inc. is the U.S. based pharmaceutical unit of Schering AG and is a division of Bayer AG.

6. Berlex, Inc. was engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Yaz®/Yasmin®.

7. At all relevant times, Defendant Bayer Healthcare Pharmaceuticals, Inc. is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drugs Yaz® and Yasmin®. At relevant times, Defendant Bayer Healthcare Pharmaceuticals, Inc. conducted and sustained regular business in Mississippi by selling and distributing its products in Mississippi and engaged in substantial commerce and business activity in Montgomery County in Mississippi.

8. Defendant Bayer Healthcare Pharmaceuticals, Inc. is the holder of the approved New Drug Application ("NDA") for Yaz®.

9. Defendant Bayer Healthcare Pharmaceuticals, Inc. is the holder of the approved New Drug Application ("NDA") for Yasmin®.

10. Bayer Healthcare, LLC is a Delaware limited liability company, with its principal place of business at 555 White Plains Road, Tarrytown, New York 10591. Bayer Healthcare, LLC was involved in the integration of Bayer Healthcare and Berlex Laboratories, Inc. (formally known as Berlex, Inc.). Bayer Healthcare, LLC is a resident of New York and is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly

through third parties or related entities, its products, including the prescription drugs Yaz®/Yasmin®.

11. Defendant Bayer Pharma AG, formerly known as Schering AG and Bayer Schering Pharma AG, respectively, is a pharmaceutical company that is organized and existing under the laws of the Federal Republic of Germany, having a principal place of business at Müllerstrasse 178, 13353 Berlin, Germany.

12. Defendant Bayer Pharma AG is a corporate successor of Schering AG.

13. Schering AG was renamed Bayer Schering Pharma AG effective December 29, 2006. Bayer Schering Pharma AG was then renamed Bayer Pharma AG effective July 1, 2011.

14. Defendant Bayer Pharma AG's headquarters and principal place of business in the United States is located at 100 Bayer Road, Pittsburg Pennsylvania 15205.

15. Defendant Bayer Pharma AG is the current owner of the patent(s) relating to the oral contraceptive, Yaz®/Yasmin®.

16. Defendant Bayer Pharma AG, is the current owner of the patent(s) relating to the oral contraceptive Yaz®.

17. Bayer AG is a German chemical and pharmaceutical company that is headquartered in Leverkusen, North Rhine-Westphalia, Germany.

18. Bayer AG is the third largest pharmaceutical company in the world.

19. Bayer AG is the parent/holding company of all other named Defendants.

20. Bayer AG's headquarters and principal places of business in the United States are located at 100 Bayer Road, Pittsburg, Pennsylvania, 15205.

21. Bayer Healthcare Pharmaceuticals, Inc. and Bayer Pharma AG are collectively referred to herein as "Bayer", “Bayer Defendants", or “Defendants.” Bayer Corporation, Bayer Healthcare, LLC, and Bayer AG, are collectively referred to herein as “other Bayer entities.”

22. This court has jurisdiction over this action pursuant to 28 U.S.C. §1332 because there is complete diversity of citizenship between the parties, and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

23. Venue is proper in this District pursuant to Pretrial Order No. 9 which authorized direct filing of cases into MDL No. 2100 in order to eliminate delays associated with transfer of cases and to promote judicial efficiency. Upon the completion of all pretrial proceedings applicable to this case, pursuant to Pretrial Order No. 9, this case will be transferred to the federal district court in the district where the Plaintiff allegedly was injured by use of Yaz®, Yasmin® or Ocella®, or where the Plaintiff resides at the time of such transfer.

FACTUAL BACKGROUND

Nature of the Case

24. Plaintiff brings this case against Defendants for damages associated with her ingestion of the pharmaceutical drug Yaz®/Yasmin® (ethinyl estradiol and drospirenone), an oral contraceptive designed, manufactured, marketed, and distributed by Defendants. Specifically, as a direct result of her use of Yaz®/Yasmin®, Plaintiff suffered a gallbladder injury.

Bayer's Combined Oral Contraceptives - Yaz®/Yasmin® and Yasmin

25. Yaz® and Yasmin® are birth control pills manufactured and marketed by Defendants. They are combination oral contraceptives, or "COCs," meaning that they contain an estrogen component and a progestin component. Together, these steroidal components work

together in COCs to suppress ovulation, fertilization, and implantation and thus prevent pregnancy.

26. Yaz® and Yasmin® were approved by the Food and Drug Administration for marketing in 2006 and 2001, respectively.

Yaz® and Yasmin® contain a "Fourth Generation" Progestin.

27. The estrogen component in Yaz® and Yasmin® is known generically as ethinyl estradiol. The progestin component is known as drospirenone. Yasmin® contains 0.03 milligrams of ethinyl estradiol, and Yaz® contains 0.02 milligrams of ethinyl estradiol. Both products contain 3 milligrams of drospirenone.

28. Yaz® and Yasmin® are different from other combined hormonal birth control pills in that they contain drospirenone, a progestin that is unlike other progestins available in the United States and was never before marketed in the United States prior to its use in Yasmin.

29. Shortly after the introduction of combined oral contraceptives in the 1960's, doctors and researchers found that women using birth control pills had a higher risk of blood clots, heart attacks, and strokes than women not using the pill. As a result, the various brands of birth control pills were reformulated to reduce the amounts of estrogen. As the amounts of estrogen levels reduced, so too did the risk of blood clots, heart attacks, and strokes.

30. During this time, new progestins were being developed, which became known as "second generation" progestins (e.g. lovenorgestrel). These second generation progestins, when combined with the lower amounts of the estrogen, ethinyl estradiol, helped to reduce the risk of blood clots, heart attacks, and strokes and were considered safer for women.

31. During the 1990's, new "third generation" progestins were developed. Unfortunately, these "third generation" progestins (e.g. gestodene and desogestrel) have been

associated with a greater risk of blood clots in the deep veins (deep vein thrombosis or "DVT") and lungs (pulmonary embolism or "PE"). As a result of this increased risk of blood clots, the FDA has required that products containing third generation progestins include a warning of the potentially increased risk of thrombosis.

32. Yaz® and Yasmin® contain the same estrogen component, ethinyl estradiol, that has been used in the lower dose birth control pills for decades.

33. However, drospirenone is a new type of progestin and is considered a "fourth generation" progestin. No other birth control pills contain drospirenone, except for a recently approved generic version of Yaz® and Yasmin® marketed under the trade name Ocella.

34. Since drospirenone is new, there is insufficient data available to support its safe use, particularly compared with second generation progestins. In fact, studies performed prior to FDA approval indicate that drospirenone has certain effects that are different from those of traditional second generation progestins, and potentially more dangerous.

35. A dangerous effect of drospirenone is that it acts as a diuretic, which can cause an increase in potassium levels in the blood. This can lead to a condition known as hyperkalemia if the potassium levels become too high. Hyperkalemia can cause heart rhythm disturbances, such as extrasystolies, pauses, or bradycardia. If left untreated, hyperkalemia can be fatal. If hyperkalemia disrupts the normal heart rhythms, the flow of blood through the heart can be slowed to the point that it permits blood clots to form. Blood clots in the heart can then lead to heart attacks, or the clots can break off and travel to the lungs where they can cause pulmonary embolism, or can travel to the brain causing stroke. The diuretic nature of drospirenone also attributes to blood clot formation elsewhere in the body.

36. An additional dangerous effect of drospirenone is that in acting as a diuretic, it affects the kidney by blocking the aldosterone receptors. Aldosterone is a hormone that increases the reabsorption of sodium and water and the secretion of potassium in the kidneys, resulting in dehydration. Dehydration, may lead to the formation of gall stones. Blocking the aldosterone receptor may also increase the levels of cholesterol in the blood. An excess of cholesterol, calcium and phosphate in the gallbladder reduces gallbladder emptying and results in gallbladder disease.

37. Upon information and belief, Defendants knew or should have known that the use of drospirenone in Yaz®/Yasmin® causes arrhythmia, cardiac arrest/heart attack, intracardiac thrombus, pulmonary embolism, deep vein thrombosis, stroke, and/or gallbladder disease.

38. During the brief time that Yaz® and Yasmin® have been sold in the United States, hundreds of reports of injury and death have been submitted to the FDA in association with Defendants' products.

39. In April 2002, the British Medical Journal reported that the Dutch College of General Practitioners recommended that older second generation birth control pills be prescribed in lieu of Yasmin® as a result of 40 cases of venous thrombosis among women taking Yasmin.

40. In February 2003, a paper entitled *Thromboembolism Associated With the New Contraceptive Yasmin*® was published in the British Medical Journal detailing a Netherlands Pharmacovigilance Centre report of five additional reports of thromboembolism where Yasmin® was suspected as the cause, including two deaths.

41. In fact, in less than a five-year period, from the first quarter of 2004 through the third quarter of 2008, over 50 reports of death among users of Yaz®/Yasmin® have been filed with the FDA.

42. These reports include deaths associated with cardiac arrhythmia, cardiac arrest, intracardiac thrombus, pulmonary embolism, and stroke in women in their child bearing years.

43. Some deaths reported occurred in women as young as 17 years old.

44. Significantly, reports of elevated potassium levels are frequently included among the symptoms of those suffering death while using Yaz®/Yasmin®.

45. Two recent studies, released in August 2009, have found significantly increased risks of harm associated with Yaz®/Yasmin® over other types of birth control pills. The first study assessed the risk of developing venous thrombosis in women who use oral contraception. The women ranged in age from 15 to 49 and had no history of heart disease or any malignant condition. The study found that of the 3.3 million women taking oral contraceptives, there were 4,213 venous thrombotic events. Of this total, 2,045 occurred in women using drospirenone oral contraceptives. The study concluded that "oral contraceptives with . . . drospirenone were associated with a significantly higher risk of venous thrombosis than oral contraceptives with evonogesterel." Lidegard, et al., Hormonal contraception and risk of venous thromboembolism: national follow up study, THE BRITISH MEDICAL JOURNAL 2009, 330: 2921.

46. The second study found that Yaz®/Yasmin® users have twice the risk of a clotting event than users of birth control pills that contain levonorgestral. Vandenbroucke, et al., The venous thrombotic risk of oral contraceptives, effects of estrogen dose and progestin type: results of the MEGA case-control study. THE BRITISH MEDICAL JOURNAL 2009, 339: B2921.

47. Despite the wealth of scientific evidence, Defendants have not only ignored the increased risk of the development of the aforementioned injuries associated with the use of

Yaz®/Yasmin®, but they have, through their marketing and advertising campaigns, urged women to use Yaz®/Yasmin® instead of birth control pills that present a safer alternative.

Over-Promotion of Yaz®/Yasmin®

48. Defendants market Yaz®/Yasmin® as providing the same efficacy as other birth control pills in preventing pregnancy, but with additional benefits.

49. However, because Yaz®/Yasmin® contain the fourth generation progestin drospirenone, they present additional health risks not associated with other birth control pills.

50. For example, prior to its sale to Bayer in 2006, Berlex Laboratories promoted Yasmin's fourth generation progestin, drospirenone, by stating, "Ask about Yasmin, and the difference a little chemistry can make."

51. In response, on July 10, 2003, the FDA objected to the characterization that drospirenone was a benefit compared to the progestin used in other combined oral contraceptives, and issued a warning letter stating, "FDA is not aware of substantial evidence of substantial clinical experience demonstrating that Yasmin® is superior to other COCs or that the drospirenone in Yasmin® is clinically beneficial. On the contrary, FDA is aware of the added clinical risks associated with drospirenone [.]"

52. The FDA's warning letter continued by stating that the advertisement failed "to communicate that the potential to increase potassium is a risk" or that "increased serum potassium can be dangerous."

53. More recently, Defendants advertised that its product Yaz®/Yasmin® was indicated for treatment of premenstrual syndrome or "PMS," as opposed to the less serious condition of premenstrual dysphoric disorder or "PMDD."

54. Defendants also advertised that Yaz®/Yasmin® contained the added benefit of preventing or reducing acne.

55. In response, on October 3, 2008, the FDA issued another warning letter to Bayer for the misleading advertisement, reiterating that the marketing was misleading because it promoted Yaz®/Yasmin® for medical conditions beyond the limits of the FDA approval, and adding that "Yaz®/Yasmin® has additional risks because it contains the progestin, drospirenone ... which can lead to hyperkalemia in high risk patients, which may result in potentially serious heart and health problems."

56. The FDA further warned in its October 3, 2008 letter that Yaz®/Yasmin® "does not result in completely clear skin" and that Defendants' "TV Ads misleadingly overstate the efficacy of the drug."

57. Indeed, the FDA felt Defendants' over-promotion was so severe that it required Bayer to run new TV advertisements to correct the previous misleading Yaz®/Yasmin® advertisements regarding acne and premenstrual syndrome.

58. Bayer ultimately agreed to spend at least $20 million on corrective TV advertisements and to submit all Yaz®/Yasmin® advertisements to the FDA for advanced screening for the next six years.

Plaintiff's Use of Yaz®/Yasmin® and Resulting Injuries

59. As a result of Defendants' claims regarding the effectiveness, safety, and benefits of Yaz®/Yasmin®, Plaintiff’s medical provider prescribed and Plaintiff began using Yaz®/Yasmin® in or about May, 2003.

60. As a direct and proximate result of using Yaz®/Yasmin®, Plaintiff suffered a gallbladder injury and removal of her gallbladder.

61. Prior to Plaintiff's use of Yaz®/Yasmin®, Defendants knew or should have known that use of Yaz®/Yasmin® created a higher risk of gallbladder injury than other oral contraceptives on the market, including but not limited to second generation oral contraceptives, and that, when taken as directed, such use was unreasonably dangerous to consumers.

62. Despite the fact that Defendants knew or should have known of the serious health risks associated with the use of Yaz®/Yasmin®, Defendants failed to warn Plaintiff and/or her health care providers of said serious risks before she used the product.

63. Had Plaintiff and/or her heath care providers known the risks and dangers associated with Yaz®/Yasmin®, she would not have used Yaz®/Yasmin® and would not have suffered the aforementioned injuries.

64. Plaintiff did not know, nor should she have reasonably discovered through the use of reasonable diligence, that Yaz®/Yasmin® wrongfully caused her gallbladder injury and that she had a claim against Defendants until less than two years prior to the date of filing this action.

65. As a direct and proximate result of her use of Yaz®/Yasmin®, Plaintiff suffered and will continue to suffer physical injury, including but not limited to, conscious pain and suffering, as a result of her injuries alleged herein.

66. As a direct and proximate result of Plaintiff's use of Yaz®/Yasmin®, Plaintiff has suffered and will continue to suffer pecuniary losses.

COUNT I

Products Liability
Defective Manufacturing
As to All Defendants

67. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

68. Defendants are the manufacturers, designers, distributors, sellers, or suppliers of Yaz®/Yasmin®.

69. The Yaz®/Yasmin® birth control pills manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants were expected to and did reach the consumer without any alterations or changes.

70. The Yaz®/Yasmin® birth control pills manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants, were defective in their manufacture and construction when they left the hands of Defendants in that they deviated from product specification such that they were unreasonably dangerous to an ordinary user or consumer and posed a serious risk of injury and death.

71. As a direct and proximate result of Plaintiff's use of Yaz®/Yasmin® as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff suffered and will continue to suffer personal injuries, economic and non-economic damages.

72. Defendants' actions and omissions as identified in this Complaint show that Defendants acted maliciously, with aggravated or egregious fraud, and/or intentionally disregarded Plaintiff's rights, so as to warrant the imposition of punitive damages.

COUNT II

Products Liability
Design Defect
As to All Defendants

73. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

74. Defendants are the manufacturers, designers, distributors, sellers, or suppliers of Yaz®/Yasmin®.

75. The Yaz®/Yasmin® birth control pills manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants were expected to and did reach the consumer without any alterations or changes.

76. The Yaz®/Yasmin® birth control pills manufactured and supplied by Defendants were defective in design or formulation in that, when it left the hands of the Defendants, the foreseeable risks of the product exceeded the benefits associated with its design or formulation, or they were more dangerous than an ordinary consumer would expect.

77. The foreseeable risks associated with the design or formulation of the Yaz®/Yasmin® birth control pills, include, but are not limited to, the fact that the design or formulation of Yaz®/Yasmin® is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner.

78. Additionally, Defendants advised consumers and the medical community that Yaz®/Yasmin® contained the same safety profile as other oral hormonal birth control pills. However, Defendants failed to adequately test the safety of Yaz®/Yasmin® versus other oral hormonal birth control pills.

79. Had Defendants adequately tested the safety of Yaz®/Yasmin® versus other oral hormonal birth control pills and disclosed the results to the medical community or the public, Plaintiff would not have used, and her physician would not have prescribed, Yaz®/Yasmin®.

80. As a direct and proximate result of Plaintiff's use of Yaz®/Yasmin® as manufactured, designed, sold, supplied and introduced into the stream of commerce by

Defendants, Plaintiff suffered and will continue to suffer personal injuries, economic and non-economic damages, including pain and suffering.

81. Defendants' actions and omissions as identified in this Complaint show that Defendants acted maliciously, with aggravated or egregious fraud, and/or intentionally disregarded Plaintiff's rights, so as to warrant the imposition of punitive damages.

COUNT III

Products Liability
Defect Due to Inadequate Warning
As to All Defendants

82. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

83. The Yaz®/Yasmin® birth control pills manufactured and supplied by Defendants were defective due to inadequate warning or instruction and was unreasonably dangerous to the ordinary user or consumer because Defendants knew or should have known that the product created significant risks of serious bodily harm and death to consumers and they failed to adequately warn consumers and/or their health care providers of such risks.

84. The Yaz®/Yasmin® birth control pills manufactured and supplied by Defendants were defective due to inadequate post-marketing warning or instruction and were unreasonably dangerous to the ordinary user or consumer because, after Defendants knew or should have known of the risk of serious bodily harm and death from the use of Yaz®/Yasmin®, Defendants failed to provide an adequate warning to consumers and/or their health care providers of the product, knowing the product could cause serious injury and death.

85. As a direct and proximate result of Plaintiff's use of Yaz®/Yasmin® as manufactured, designed, sold, supplied and introduced into the stream of commerce by

Defendants, Plaintiff suffered and will continue to suffer personal injuries, economic and non-economic damages.

86. Defendants' actions and omissions as identified in this Complaint show that Defendants acted maliciously, with aggravated or egregious fraud, and/or intentionally disregarded Plaintiff's rights, so as to warrant the imposition of punitive damages.

COUNT IV

Negligence
As to All Defendants

87. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

88. Defendants had a duty to exercise reasonable care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions and distribution of Yaz®/Yasmin® into the stream of commerce, including a duty to assure that its product did not pose a significantly increased risk of bodily harm and adverse events. Defendants also had the duty to ensure that all of its communications to consumers, including Plaintiff and her healthcare providers, were truthful.

89. Defendants failed to exercise ordinary care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions and distribution of Yaz®/Yasmin® into interstate commerce and in communications regarding Yaz®/Yasmin® in that Defendants knew or should have known that the product caused such significant bodily harm or death and was not safe for use by consumers.

90. Defendants further failed to exercise ordinary care in the labeling of Yaz®/Yasmin® in that Defendants failed to issue to consumers and/or their health care providers adequate warnings of the risk of serious bodily injury or death due to the use of Yaz®/Yasmin®.

91. Plaintiff and her healthcare providers reasonably relied to Plaintiff's detriment upon Defendants' misrepresentations and/or omissions in its labeling, advertisements, and promotions concerning the serious risks posed by the product, including that Yaz®/Yasmin® was as safe or safer than other types of oral contraceptives for human consumption and/or use and that Defendants' labeling, advertisements and promotions fully described all known risks of the product.

92. Despite the fact that Defendants knew or should have known that Yaz®/Yasmin® posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market Yaz®/Yasmin® for use by consumers.

93. Defendants knew or should have known that consumers, including Plaintiff, would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

94. As a direct and proximate result of Defendants' negligence, Plaintiff suffered and will continue to suffer personal injuries, economic and non-economic damages.

COUNT V

Fraud
As to All Defendants

95. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

96. Defendants are the manufacturers, designers, distributors, sellers or suppliers of Yaz®/Yasmin® and made representations to Plaintiff and her healthcare providers regarding the character or quality of Yaz®/Yasmin® for guidance in their decision to select Yaz®/Yasmin®.

97. Specifically, Defendants represented that Yaz®/Yasmin® was just as safe or safer, and just as effective or more effective, than other birth control products on the market.

98. Defendants' representations regarding the character or quality of Yaz®/Yasmin® were untrue.

99. Defendants had actual knowledge based upon studies, published reports and clinical experience that its product Yaz®/Yasmin® created an unreasonable risk of serious bodily injury and death to consumers, or should have known such information.

100. Defendants fraudulently misrepresented or omitted this information in its product labeling, promotions and advertisements and instead labeled, promoted and advertised its product as safe or safer than, and as or more effective than, other types of oral contraceptives in order to avoid losses and sustain profits in its sales to consumers.

101. Plaintiff and her healthcare providers reasonably relied to Plaintiff's detriment upon Defendants' misrepresentations and/or omissions in its labeling, advertisements, and promotions concerning the serious risks posed by the product. Plaintiff reasonably relied upon Defendants' representations to her and/or her healthcare providers that Yaz®/Yasmin® was safer than other types of oral contraceptives for human consumption and/or use and that Defendants' labeling, advertisements and promotions fully described all known risks of the product.

102. As a direct and proximate result of Defendants' fraudulent misrepresentations or omissions, Plaintiff suffered and will continue to suffer personal injuries and economic and non-economic damages, including pain and suffering.

103. Defendants' actions and omissions as identified in this Complaint demonstrate malicious actions, aggravated or egregious fraud, and/or intentional disregard of Plaintiff's rights so as to warrant the imposition of punitive damages.

COUNT VI

Breach of Express Warranty
As to All Defendants

104. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

105. The Bayer Defendants expressly warranted that Yaz®/Yasmin® was a safe and effective prescription contraceptive.

106. The Yaz®/Yasmin® birth control pill manufactured and sold by Defendants did not conform to these express representations because it caused serious injury to consumers when taken in recommended dosages.

107. As a direct and proximate result of the Bayer Defendants' breach of warranty, Plaintiff has suffered harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

108. Defendants' actions and omissions as identified in this Complaint demonstrate malicious actions, aggravated or egregious fraud, and/or intentional disregard of Plaintiff's rights so as to warrant the imposition of punitive damages.

COUNT VII

Breach of Implied Warranty
As to All Defendants

109. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

110. At the time the Defendants designed, manufactured, marketed, sold, and distributed Yaz®/Yasmin® for use by Plaintiff, Defendants knew of the use for which Yaz®/Yasmin® was intended and impliedly warranted the product to be of merchantable quality and safe for such use.

111. Plaintiff reasonably relied upon the skill and judgment of the Defendants as to whether Yaz®/Yasmin® was of merchantable quality and safe for its intended use and upon the Defendants' implied warranty as to such matters.

112. Contrary to such implied warranty, Yaz®/Yasmin® was not of merchantable quality or safe for its intended use, because the product was reasonably dangerous as described above.

113. As a direct and proximate result of the Defendants' breach of warranty, Plaintiff has suffered harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

114. Defendants' actions and omissions as identified in this Complaint demonstrate malicious actions, aggravated or egregious fraud, and/or intentional disregard of Plaintiff's rights so as to warrant the imposition of punitive damages.

COUNT VIII

Violation of the Deceptive Trade Practices Act
As to all Defendants

115. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

116. Defendants violated the Deceptive Trade Practices Act ("DTPA") of the state in which Plaintiff resides by the use of false and misleading misrepresentations or omissions of material fact in connection with the marketing, promotion, and sale of Yaz®/Yasmin®.

117. Defendants communicated the purported benefits of Yaz®/Yasmin® while failing to disclose the serious and dangerous side effects related to the use of Yaz®/Yasmin® with the intent that consumers, like Plaintiff, and their healthcare providers rely upon the omissions and misrepresentations and purchase or prescribe Yaz®/Yasmin®, respectively.

118. As a result of violating the DTPA, Defendants caused Plaintiff to be prescribed and to use Yaz®/Yasmin®, causing severe injuries and damages as previously described herein.

119. As a result of Defendants' violations of the DTPA, Plaintiff seeks treble damages and costs as provided by the DTPA.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief as follows:

1. Compensatory damages in excess of the jurisdictional amount, including, but not limited to non-economic damages in excess of $75,000.00;
2. Medical expenses and other economic damages in an amount to be determined at trial of this action;
3. Attorneys' fees, expenses, and costs of this action;
4. Such further relief as this Court deems necessary, just, and proper.

JURY DEMAND

Plaintiff hereby demands a trial by jury on all issues so triable.

RESPECTFULLY SUBMITTED,

DANZIGER & DE LLANO, LLP

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